JUL 16 2003

K031376
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SUMMARY OF SAFETY AND EFFECTIVENESS

April 29, 2003

DINAMAP® PRO 1000 V3 Monitor

A. Submitter

GE Medical Systems Information Technologies
4502 Woodland Corporate Boulevard
Tampa, FL 33614

B. Company Contact

Melissa Robinson
Regulatory Affairs Specialist
Phone: 813-887-2133
Fax: 813-887-2552

C. Device Name

Trade Name: PRO 1000 V3 Monitor
Common Name: Physiological Monitor, Patient Monitor

Classification/Device Product Code:

21 CFR 870.1130 System, Measurement, Blood Pressure, Noninvasive	DXN
21 CFR 870.1110 Computer, Blood Pressure	DSK
21 CFR 870.1100 Alarm, Blood Pressure	DSJ
21 CFR 870.1100 Monitor, Blood Pressure, Indwelling	CAA
21 CFR 870.2700 Oximeter	DQA
21 CFR 870.2710 Oximeter, Ear	DPZ
21 CFR 880.2910 Thermometer, Clinical Electronic	FLL
21 CFR 870.2300 Monitor, Cardiac (including cardiotachometer & rate alarm)	DRT
21 CFR 870.2340 Electrocardiograph	DPS
21 CFR 870.2350 Adapter, Lead Switching, Electrocardiograph	DRW
21 CFR 870.1025 Arrhythmia Detection and Alarm	DSI
21 CFR 868.2375 Monitor, Breathing Frequency	BZQ
21 CFR 870.1025 Recorder, Paper Chart	DSF

D. Predicate/Legally Marketed Devices

DINAMAP® PRO 1000 V2 – K012915
GE Medical Systems Information Technologies

E. Device Description

The DINAMAP® Pro 1000 V3 Monitor is intended to monitor a single patient's vital signs in the hospital, outpatient surgery and healthcare practitioner facilities. The patient populations include adult, pediatric, and neonatal. The device's networking capabilities include connection to a central station via VHF, 900 MHz or hardwire communication; host communications for use with other devices. In addition, the DINAMAP Pro 1000 Monitor may be operated from internal batteries making the device portable and suitable for intra-hospital transport.

F. Intended Use

The DINAMAP® Pro 1000 V3 Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. The Pro 1000 Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

G. Technological Characteristics

The DINAMAP® PRO 1000 V3 Monitor has the same technological characteristics as the predicate device, the DINAMAP® PRO 1000 V2 Monitor. There are no new technologies used on the DINAMAP® PRO 1000 V3 Monitor.

H. Testing

Several bench studies were conducted which demonstrate safety and effectiveness of the DINAMAP® PRO 1000 V3 Monitor:

- Electromagnetic Compatibility
- Electrical Safety
- Mechanical and Environmental

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2003

GE Medical Systems Information Technologies
c/o Ms. Melissa Robinson
Regulatory Affairs Specialist
4502 Woodland Corporate Boulevard
Tampa, FL 33614

Re: K031376
Trade Name: PRO 1000 V3 Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: June 12, 2003
Received: June 17, 2003

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031376

Device Name: DINAMAP® PRO 1000 V3 Monitor

Indications for Use:

The DINAMAP® Pro 1000 V3 Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. An additional feature is the detection of three lethal arrhythmias- asystole, ventricular tachycardia (v-tach), and ventricular fibrillation (v-fib).The Pro 1000 V3 Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031376